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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,898	07/30/2002	Tugrul T. Kararli	6794S-000005USC	8229

7590 12/14/2004

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EXAMINER	
AZPURU, CARLOS A	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,898	KARARLI ET AL.	
	Examiner	Art Unit	
	Carlos A. Azpuru	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-26 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the preliminary amendment filed 07/20/2002. It is also noted that three information disclosure statements were filed on 12/13/2002. Although all the references were reviewed, only one of the information disclosure statements was scanned into the EDAN system and available for acknowledgement.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-58 of copending Application No. 09/874,504 (US'504). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'504 claims an oral pharmaceutical of COX-2 inhibitors comprising a drug particle with a D90 particle size between 0.01 um and 200 um (see claim 1). The

percentage of particles smaller than 1 um is between 25% and 100% (see claim 2). There may also be 25% to 100 % of the particles with a size between 450 nm and 1000 nm (see claim 3). The structure of the compound of claim 15 is the same as that of claims 1 and 10of the instant application. Substituted ring systems and the particular COX-2 inhibitors are listed at claims 16-18. The unit dosage is set out in claim 19. A method of analgesia, which is a method of treating a COX-2 disorder, are set out in claims 20-28, 46-54, 57 and 58. Therefore, those of ordinary skill would have expected similar therapeutic results from the instant composition and method of treating given the claims of US'504 which sets out a similar composition, and for the treatment of a well known Cox-2 related disorder such as pain. There are no unusual and/or unexpected results which would rebut prima facie obviousness. The instant claims would have therefore been obvious given the claims of US'504.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-58 of copending Application No. 10/113,157 (US'157). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'157 claims an oral pharmaceutical of COX-2 inhibitors comprising a drug particle with a D90 particle size between 0.01 um and 200 um (see claim 1). The percentage of particles smaller than 1 um is between 25% and 100% (see claim 2). There may also be 25% to 100 % of the particles with a size between 450 nm

and 1000 nm (see claim 3). The structure of the compound of claim 15 is the same as that of claims 1 and 10 of the instant application. Substituted ring systems and the particular COX-2 inhibitors are listed at claims 16-18. The unit dosage is set out in claim 19. A method of analgesia, which is a method of treating a COX-2 disorder, are set out in claims 20-28, 46-54, 57 and 58. Therefore, those of ordinary skill would have expected similar therapeutic results from the instant composition and method of treating given the claims of US'504 which sets out a similar composition, and for the treatment of a well known Cox-2 related disorder such as pain. There are no unusual and/or unexpected results which would rebut prima facie obviousness. The instant claims would have therefore been obvious given the claims of US'157.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Liversidge et al (WO 93/25190) is cited as a patent of interest in its disclosure of NSAID compositions with particle sizes of less than 400 nm.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CARLOS A. AZPURU
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